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Recruits

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13. ABSTRACT (Maximum 200 Words) The United States Marine Corps (USMC) has the highest tobacco use rates of all of the Services. About 41% of entering USMC recruits are smokers, and 20% use smokeless tobacco. Although recruits are prohibited from using all forms of tobacco during basic training, post-graduation relapse rates are high, and a proportion of nonusers initiate tobacco use following graduation from boot camp. Adding a minimal intervention to the tobacco ban could provide significant benefits in long-term tobacco cessation among new USMC personnel. The primary objective of this study is to develop and evaluate a brief, video-based, tobacco cessation intervention that is tailored for the Marine Corps and practical for delivery in the training environment. Approximately 200 platoons (N = 15,000 - 18,000 recruits) will be randomly assigned to either the Intervention (I) or Control(C) group. The first video (I1 or C1) will be presented near the end of basic training; the second video (I2 or C2) will be presented when the new graduates report to the School of Infantry a few weeks after basic training. Three and 12- month follow-up surveys on tobacco use will be mailed to all participants. Results will be analyzed for the effects of the videos on participants' tobacco use, quit attempts, and stage of change.				
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INTRODUCTION

The United States Marine Corps (USMC) has the highest tobacco use rates of all of the Services.¹ About 41% of entering Marine Corps recruits are smokers, and 20% use smokeless tobacco; many use both.² Although recruits are prohibited from using all forms of tobacco during basic training, post-graduation relapse rates are high, and a proportion of nonusers take up the habit following graduation from boot camp.² Adding a tobacco-cessation intervention to the tobacco ban could help educate and motivate recruits to remain tobacco-free.

This project will develop and test a brief, self-contained, video-based, tobacco cessation intervention tailored specifically for Marine Corps recruits and designed for easy administration to the populations at the Marine Corps Recruit Depot (MCRD) and the USMC School of Infantry (SOI). The video intervention will build on the existing tobacco ban by providing information, advice, graphic imagery, testimonials, and cognitive/behavioral skills to help educate, motivate, and support recruits in choosing to maintain their abstinence from tobacco. The program will consist of two short (16 - 18 min) tobacco cessation videos. The first will be shown at the end of basic training, the second about 2-3 weeks later at the beginning of infantry training. Thus, the two videos will bracket the post-graduation liberty period, which is when most smoking recidivism occurs. A randomized, controlled design will be used to evaluate the effectiveness of the intervention. Baseline survey data collection will run for one year, and approximately 15,000 - 18,000 participants are expected to enroll in the study. Outcomes data collection will be conducted via two follow-up surveys, one after 3 months, the other after 12 months.

BODY

Conduct in-depth literature review

Tobacco Use in the Military. The Department of Defense spends an estimated \$875 million on medical treatment and lost productivity associated with regular tobacco use.³ Between 30% and 40% of military personnel currently use tobacco, with the highest rates of both cigarette and smokeless tobacco use occurring in the Marine Corps.¹ Reducing the relatively high prevalence of tobacco use in the military is a current priority of the DoD as well as an important national health goal.^{1,4}

Smokers have significantly higher attrition rates than nonsmokers do, both in boot camp and during the first year of service.^{5,6} More importantly, the use of cigarettes, chewing tobacco, or snuff causes meaningful deficits in operational readiness of recruits⁷⁻⁹ and active duty personnel.¹⁰⁻¹³ A pronounced, negative dose-response relationship obtains between smoking and physical performance,¹¹ and tobacco use is one of the most significant modifiable risk factors for training injuries.^{7, 14, 15} Smokers also have more illnesses, higher hospitalization rates, greater risk of infection, and slower recovery times, all of which translate into more sick days or limited duty and lost productivity for the operational command.¹⁶ Repeated

tobacco use is highly associated with subsequent addiction, a process that is typically seen in teens and young adults.^{17, 18} Long-term cigarette smoking or tobacco chewing causes premature death and many negative health consequences.^{19, 20}

All of the problems associated with tobacco are preventable if the individual can stop using tobacco or avoid starting, especially early in life.²¹ Although historically the military has supported and even glamorized smoking,³ steps have been taken in recent years to reduce tobacco use.^{1, 22} However, the prevalence of tobacco use remains high in the armed forces, and therefore much more needs to be done.^{1, 23} Because the military is a large and diverse organization, any effort to reduce the overall prevalence of tobacco use must be carefully integrated with basic military structure and culture.^{3, 5}

The basic training environment of new recruits presents a unique opportunity to implement a tobacco cessation program.^{5, 24} All branches of the military mandate a total ban on possession and use of tobacco products during recruit training, which for the Marine Corps means a 3-month ban -- the longest of all of the services.¹⁵ It is encouraging that most recruit users would like to quit using tobacco, and many have already tried to quit on their own.^{1, 2} Unfortunately, nothing is currently being done to capitalize on the tobacco ban by supporting continued abstinence after basic training. Such support is needed because periods of enforced cessation generally are followed by relapse to tobacco use.^{6, 25, 26} Thus, there is pressing need for application of evidence-based guidelines for intervention recommended by the Agency for Health Care Policy Research (AHCPR)^{27, 28} to facilitate lasting tobacco cessation after the recruits leave basic training.²⁹

Bans and Tobacco Use. Partial or total bans on tobacco use in the home, the workplace or public facilities such as hospitals are associated with substantial increases in short- and long-term tobacco cessation.³⁰⁻³³ The bans are particularly effective as a public health strategy because they are inexpensive and impact large numbers of smokers. In the long-term, bans can promote an anti-tobacco culture in the military.³ Two studies indicate that the total ban on tobacco use during basic military training facilitates long-term cessation among new recruits.^{6, 25} However, these studies also report high rates of relapse to tobacco use following recruit training. Also, many individuals who were tobacco-free just before recruit training started to use tobacco after they graduated. A longitudinal study of Air Force recruits showed that the overall prevalence of tobacco use increased from 29% among new recruits to 37% in the same individuals one year after the end of the recruit ban.⁶ Smoking initiation was especially high (43%) among those who were ex-smokers before basic training. Thus, a ban can be an essential element to a large-scale effort to reduce the prevalence of tobacco use, but there is clear need for additional efforts to treat relapse and initiation of tobacco use.²⁹

Successful tobacco cessation involves complex behavioral and cognitive changes on the part of the individual user.³⁴⁻³⁶ A workplace or other external ban on tobacco use guarantees short-term behavioral change but not necessarily cognitive or motivational changes.^{37, 38} If there is not concomitant motivational and cognitive change, tobacco cessation may last only as long as the external tobacco ban. For instance, pregnant women frequently stop smoking to protect the health of the fetus, but the vast majority of these women later start smoking

again within several months after childbirth.^{39, 40} Previous studies of military recruits suggest a similar process of relapse occurs soon after the end of the tobacco ban.^{2, 41} From a learning theory perspective, tobacco cessation practiced in a unique and prescribed environment such as basic training seems unlikely to continue outside of that environment.⁴²

Individuals who voluntarily or involuntarily experience some form of ban on their tobacco use may be susceptible to additional intervention. They certainly have changed their tobacco use, and some have developed new negative attitudes about smoking.⁴¹ These changes in behavior and motivation leave the individual open to intervention.^{36, 43} But, if left alone following a ban, the individual is likely to return to regular tobacco use. S/he may lose the motivation to stay quit; even if motivated, s/he is unlikely to have the appropriate skills to cope with the environmental and psychological pressures that lead to relapse. However, if the individual receives appropriate help during this period of ambivalence about tobacco use, then s/he has increased chances of long-term cessation.³⁶

Why Target New Recruits for Tobacco Cessation Intervention? The basic training environment and new military recruits should be the starting point for any systematic effort by the military to reduce smoking prevalence. As mentioned, the ban on smoking during basic training presents an excellent opportunity for additional intervention to succeed. In basic training, new recruits are undergoing a transformation; they are required to learn many new behaviors and ways of thinking in order to assimilate military culture and standards. Thus, this a good time to expose the recruits to information and assistance for tobacco cessation because it is a process that also requires behavioral and cognitive changes.^{35, 36} In general, tobacco interventions are more effective among those who have reduced consumption⁴⁴ and who, for whatever reason, are contemplating taking action about their tobacco behavior.⁴³ Lifestyle changes such pregnancy for female smokers present similar opportunities for smoking cessation; women who quit smoking when they are pregnant have increased chances of long-term cessation.⁴⁵

The military should not only make a statement that tobacco use is incompatible with its culture but should also expose new recruits to current, evidence-based instruction and assistance^{27, 28} to help them achieve a tobacco-free lifestyle. The timing of the intervention should be carefully planned to access the recruits at the end of basic training and shortly thereafter when they begin their next assignment. It is clear from the past research that this is a period of high probability of relapse and initiation of smoking.⁶ Thus, the recruit should be treated as if s/he just quit immediately after basic training even though s/he has been tobacco free for six to twelve weeks. Relapse rates are highest just after the quitting and therefore this is a time when assistance and intervention should be applied.^{46, 47}

Interventions for Smoking Cessation during Basic Training. The military has banned possession and use of tobacco during recruit training for many years.⁵ The limitations of bans have been noted. Yet there have been few attempts to study the effects of providing an adjunctive intervention to the ban on tobacco use.^{6, 41, 48}

Conway et al.⁴¹ studied the effects of alternative interventions for prevention of relapse following basic training in female Navy recruits. These researchers hypothesized that

timely support following basic training might decrease the numbers of women who returned to tobacco use in the year following basic training. The recruits received either (1) encouragement to use a successful and free telephone helpline for counseling on how to stay quit, or (2) proactive monthly mailings of written information that provided tips on how to avoid relapse. Women in the control group received no further support after basic training. Unfortunately, neither the mailouts nor the telephone intervention reduced relapse rates relative to control. Women in all three groups reported the same prevalence of smoking after one year.

The Conway study highlighted an important issue, namely that tobacco interventions should address the high rates of relapse following basic training. But the impact was minimal, possibly because the written material was provided too long after the recruits left training and may not have been personalized or tailored to the individual recruits.⁴³ The telephone helpline might have provided an important source of support but almost none of the women used it, a finding that is consistent with previous research on reactive telephone quitlines.⁴⁹

Neither systematic mailouts nor telephone interventions may be feasible for implementation in a large military population because they require substantial additional resources and manpower. After graduation from basic training, the recruits quickly move to different locations and work circumstances. A more practical approach would be to administer a brief, standardized intervention to all recruits while they are in basic training. A recent study of Air Force recruits showed promising results of a computer/video-based intervention for tobacco cessation.⁶ Flights of approximately 50 recruits were randomly assigned to view either an interactive, computer-based video on tobacco cessation or a health-related video that did not address tobacco or drug use. Although there was no overall effect on smoking after one year, the intervention almost doubled the rate of tobacco cessation in the subgroup of recruits who initially reported that they had no plans to remain tobacco-free after basic training.

Preliminary Data on Tobacco Use by Marines Recruits at MCRD. The 1998 DoD survey on health related behaviors showed that smoking prevalence among Marines was about 35%, the highest of all military services.¹ Younger Marines aged 18 to 25 reported smoking prevalence of almost 45%, and use of tobacco products (e.g., chew or cigars) was also highest in the Marines Corps. Currently, there is no systematic tobacco cessation program targeting new Marine recruits. The relatively high use of tobacco demonstrates urgent need for research to develop interventions appropriate for large numbers of Marines, especially young enlisted personnel. Approximately half of tobacco users say they want to quit or have tried to quit during the last year, so new interventions should be received positively.¹

As background for the present study, 858 new male recruits completed tobacco use questionnaires at the proposed study site, the Marine Corps Recruit Depot (MCRD) in San Diego.² Data were collected between April and December of 1998. Over 90% of recruits were between 18 and 22 years of age; approximately 67% were Caucasian; over 90% had completed high school education or the equivalent. Approximately 41% of these recruits were identified as current smokers, and about half of these young smokers reported having made an effort to quit in the past. Although almost all of those surveyed believed that

tobacco negatively affects health, nearly half of the smokers said they would consider resuming smoking after basic training. Preliminary follow-up data revealed an actual reinitiation rate of 40% within 30 days after recruit training. A second survey was conducted on a different group of recruits several months after they had completed basic training. Over 90% of those who were smokers before basic training reported relapse, i.e., they resumed tobacco use after basic training. These preliminary data are generally consistent with previous studies mentioned earlier.^{1, 41} Overall the data demonstrate the need for an intervention that will provide instruction, motivation, preparation and assistance for self-monitored tobacco cessation and relapse prevention.

Conceptual Framework for Marine Corps Intervention. Ideally, a practical and clinically sound intervention like the one used by the Air Force could be developed to accompany the recruit ban on tobacco use in all branches of the military, including the Marine Corps. Were the intervention to include a "booster" component soon after the recruits leave basic training, it would address the virtual certainty of slips or relapse to tobacco use that occur during their post-graduation liberty. This is precisely the rationale used in the proposed study. In general, interventions for tobacco cessation increase in effectiveness with the number of sessions,^{27, 28} particularly when the additional sessions coincide with periods of high risk for relapse.⁴⁷ The addition of a second video-based component at the beginning of SOI, where all recruits report following basic training, should enhance the overall impact of the intervention on tobacco use and attitudes.

Videos are a convenient mode for presenting self-help instruction in support of a complex intervention.⁵⁰⁻⁵³ The tobacco-cessation videos will be based on successful program components and current smoking-cessation guidelines^{27, 28, 53} and will be tailored specifically for Marine Corps recruits. In addition, the intervention will be preceded by a 12-week ban on tobacco use and will be delivered at two critical points during a relapse-sensitive period. This approach will incorporate essential clinical elements of cognitive-behavioral treatment³⁵ into a minimal intervention strategy. Perhaps most important is that the intervention is practical for delivery to large numbers of individuals. The combination of effective clinical material and large-scale distribution will optimize the effect on the overall prevalence of tobacco use by new Marines.

Hire Project Manager, Research Assistants

The Principal Investigator, Co-Investigators, and consultant positions have all been filled. The staff includes military, Civil Service, and civilian contract scientists. Research Assistants needed for Year 2 of the project have been identified, and delivery orders have been submitted, pending receipt of Year 2 funding.

Award contract for video production

Four professional production companies in the San Diego area were interviewed, and Time Zone Video Productions was awarded the contract to produce the two tobacco-cessation

videos. Time Zone has been in business for 20 years, producing video and multimedia programming for military, law enforcement, and corporate applications. Their facility includes a large studio stage, state-of-the-art digital cameras, and nonlinear edit suites. Time Zone has produced health and fitness "how-to" programs for local medical groups, and they have expertise working with military and law enforcement clients both locally and nationwide. Past clients include the U.S. Army, U.S. Navy, SPAWAR, San Diego Sheriff, Nokia, and Qualcomm

Conduct informal focus groups with Marine Corps recruits

As part of the "search and discover" preparatory phase of the project, several small, informal discussion groups were conducted with new Marines at Camp Pendleton, CA, and Camp Lejeune, NC. The Clinical Director of a university-based smoker's helpline served as a consultant for these discussions, helping to develop questions and participating in the informal interviews. The Marine Corps participants were convenience samples of young men and women who had recently graduated from boot camp. They agreed to talk with our staff about their tobacco use and attitudes and were given permission by their supervising officers to speak with us for a few minutes. Although the staff interviewers took brief notes during the discussions, no formal data collection occurred, and the participants remained essentially anonymous. In addition, their supervising officers remained out of earshot, which gave the volunteers further encouragement to speak freely.

Overall, we conducted nine such informal discussion groups: seven with men at Camp Pendleton, and two with women at Camp Lejeune. A varied range of ages (18 - 23 yrs), ethnic backgrounds (White, Black, Hispanic, Filipino, Asian, American Indian, mixed) and tobacco use history (smokers, dippers, former users, nonusers) were represented in the groups. The groups ranged in size from four to nine participants.

A fairly consistent picture emerged from these discussions. The majority of our interviewees used or had used tobacco, but not heavily. Most had started smoking in their early- to mid-teens. Smokeless tobacco users tended to start younger and felt that dip or chew was safer than cigarettes. Some users switched back and forth, chewing when it was convenient or when smoking was prohibited, then using cigarettes when they started getting sores in their mouths from the smokeless tobacco. One young woman told us that her father used dip and had introduced her to it when she was 13 years old. Although the participants had quit tobacco without without difficulty under the mandatory tobacco ban during basic training, most had resumed their habit after graduation -- even enduring the dizziness, bad taste, burning throat, and shortness of breath that resumption entailed. A number of participants told us that their families bought them their cigarettes as a gift or a treat. One said that his grandfather talked about how they would have a cigarette together after he graduated from boot camp. Almost all claimed that they "should quit" or "will quit," and some had tried sincerely but unsuccessfully to do so. For many, tobacco use was a simply habit that they accepted and thought little about: "I do it just to do it;" "I know I shouldn't, but I do;" "I smoke because I can." When pressed for a reason, two explanations were

offered repeatedly: social interaction ("You smoke with your friends") and boredom ("You'd freak here without cigarettes" "It's something to do.")

The groups were well aware that tobacco causes a number of health problems. Many of the smokers had noticed the difference in the way their lungs felt when exercising after quitting (during boot camp), and then after starting again following graduation. But young bodies are strong and resilient, and some smokers pointed out that their run times on scored physical training (PT) tests had not been affected. When the participants were asked what might convince them to stay tobacco-free, there was general agreement that graphic images of some of the more dire health consequences of tobacco use, such as black lungs or cancerous tumors, would be motivating. Several Marines noted that they had watched family members become sick or die of smoking-related illness, and that the experience had convinced them that they should quit (or remain nonsmokers).

Men and women basically shared the same attitudes about tobacco. They acknowledged that tobacco use was a distasteful and unhealthy habit, and all but a few expressed a desire or intention to quit. But they were ambivalent about actually doing so, because tobacco served a social and/or psychological purpose in their lives. Both sexes, whether users or nonusers themselves, indicated that they preferred dates or romantic partners who did not use tobacco. Interestingly, both sexes were more critical of women who smoked. With one exception, smokeless tobacco was used only by men. Dippers were generally less concerned about health and fitness issues than were smokers, but they were very sensitive to the unsavory elements of "spit tobacco" use, particularly in the eyes of their girlfriends. Using tobacco for weight control was not a big issue for these newly-graduated Marines, who were all in excellent physical condition. However, at least one woman and one man volunteered that they were concerned about gaining weight if they were to quit smoking. When asked about continuing to smoke if they were to become pregnant, all of the women declared that they would definitely stop -- "then."

These discussion groups were invaluable in helping us understand our target audience. The candid personal stories and opinions of our courteous young participants provided many insights and ideas that subsequently lent shape to the intervention videos.

Develop intervention videos; purchase control videos

The core task for Year 1 of the project was to develop two tobacco-cessation videos tailored specifically for Marine Corps recruits/new Marines and the constraints of the operational training environment. Both videos are in the final stage of editing and will be completed by 31 May 2002.

The crux of the video intervention is to eliminate or reduce recidivism to, or initiation of, tobacco use following graduation from Marine Corps basic training. While the most successful programs are also the most intensive^{27, 46} -- usually with weekly classes for an hour or two over a period of several weeks, combined with personal counseling, workbooks, support groups, nicotine patch, and so forth -- such a program is not feasible in the recruit

training environment. Therefore, we are taking a public health approach, attempting to reach the broadest possible audience with a brief, compelling message that does not require any special staffing, medical or otherwise.⁵⁴

The content and style of the message must be suitable to this approach, as well as to the target audience of young Marines. To this end we have utilized informal discussions with newly graduated Marines, input from USMC officers at both MCRD and SOI, and a review of evidence-based tobacco-cessation literature, with special attention to research involving adolescents, to guide our selection of video elements. Basically, the elements fall into two broad categories: motivation and skills training. We hope to persuade our viewers to *want* to quit (or remain tobacco-free), and we need to show them how to do it.

In terms of motivation, the videos will (1) demonstrate how tobacco damages the body and lowers physical fitness; (2) address the issue of nicotine addiction; (3) deglamorize social tobacco use; (4) illustrate the monetary expense of a tobacco habit; (5) point out that tobacco use is incompatible with Marine Corps values of cleanliness, discipline, fitness, and readiness; and (6) encourage viewers to capitalize on the tobacco ban to maintain their new level of physical and psychological development.

In terms of skills training, the videos will (1) help viewers discover their own personal reasons for becoming/remaining tobacco-free; (2) identify common relapse risk factors or situations; (3) demonstrate strategies for dealing with risk situations; (4) suggest tobacco-cessation aids, such as the nicotine patch,⁵⁵ pure mint snuff, and Internet support websites.

The videos scripts were developed to target users, former users, and nonusers; both men and women; and both smokers and smokeless tobacco users. Video 1 (MCRD) is primarily motivational, the intention being to convince recruits, who have not used any tobacco products for at least 3 months, to remain nonusers. Video 2 (SOI) is primarily skills training, in recognition of the fact that boot camp graduates usually return to, or initiate, tobacco use during their post-graduation liberty period.² However, both motivation and strategies are addressed in both videos. The first video was produced in "cinema verite" style, in which all but a few of the roles are real-life Navy and Marine Corps personnel. The second video is a dramatic treatment representing real-life Marines who are discussing quitting tobacco, with two of the four roles assumed by nonmilitary professional actors. The scripted scenes in both videos were shot on location in San Diego at MCRD, the Naval Medical Center, and the Army National Guard Armory. In addition, the first video includes clips from interviews with students at SOI, Camp Pendleton, and SOI, Camp Lejeune.

The two scripts were reviewed and approved by MCRD, San Diego, and SOI, Camp Pendleton, and were informally reviewed and approved by the Public Affairs Officer (PAO) at SOI, Camp Lejeune. Primary reviewers included the G-3 Office, MCRD; PAO, MCRD; Recruit Training Regiment (RTR), MCRD; S-3 Office, SOI; PAO, SOI; dental and pulmonary physicians at the Naval Hospital, San Diego; and a tobacco cessation educator/clinician at the MCRD Clinic.

Evaluation of the effectiveness of the video intervention will be conducted using a randomized controlled design. Two control videos have been selected to match, as closely as possible, the length, health education purpose, military appeal, and realistic style of the intervention videos, but without addressing the intervention topic of tobacco use. The first control video consists of interviews with three military personnel (two men, including a Marine, and one woman) who are heterosexual and HIV-positive. The second control video is a dramatic treatment of three male Marines on their way to a foreign port; the topic is sexually-transmitted diseases.

Submit stub requisitions for mailout materials, printing

After conducting a broad search of 19 local data services companies, comparing bids, and weighing other relevant factors such as experience and proximity to MCRD and NHRC, we selected an excellent company and submitted a sole source requisition document to obtain their services for printing and data entry of the baseline questionnaire and consent form. At this time we are awaiting award of the contract. Mailing envelopes have been purchased and delivered.

Develop and print baseline questionnaires

The purpose of the tobacco intervention is to accomplish the following, as appropriate: reduce or eliminate tobacco use among users; prevent initiation of, or relapse to, tobacco use among nonusers; increase the number of quit attempts among users; and increase motivation to quit/remain tobacco free. The efficacy of the intervention will be evaluated by measuring changes in tobacco-related behaviors and attitudes over a one-year period. Data collection will be accomplished using self-report surveys completed at baseline, after 3 months, and after 12 months.

In addition to basic demographic data, the main variables needed for outcomes assessment include the following: any use (of tobacco products); regular use; age started using regularly; current use; amount used (both cigarettes and smokeless); reasons to use/not use; dependency; withdrawal symptoms; psychological symptoms; stage of change; intention to quit; desire for help in quitting; beliefs about health effects; beliefs about impact on physical performance; physical activity level; use by platoon leaders.

In developing the baseline questionnaire, we reviewed a number of survey instruments and scales that have been used by the DoD to assess lifestyle behaviors, including tobacco use. These instruments included the Health Enrollment Assessment Review (HEAR)⁵⁶, DoD Survey of Health Behaviors Among Military Personnel,¹ Operation Stay-Quit Follow-up Survey,⁴¹ Millennium Cohort Survey,⁵⁷ Recruit Assessment Program (RAP),⁵⁸ U.S. Navy Follow-up for Fitness Questionnaire,⁵⁹ Fagerstrom Nicotine Dependency Test,⁶⁰ Stages of Change scale,⁴³ and the population surveys used in the California Tobacco Control Program.¹⁷ We selected items from these sources that addressed the targeted outcome measures.

Because the training schedule at MCRD is time-impacted to an extraordinary degree, it was important to design the baseline questionnaire to be as brief as possible, while covering the key outcome variables. The final questionnaire is a 2-page instrument that takes approximately 5 minutes to complete (see Appendix B). The instrument has been reviewed and approved by the Marine Corps Manpower and Reserve Affairs survey office. Baseline data collection is scheduled to begin 26 June 2002; the printing stub requisition has been submitted (see previous section), and the questionnaires will be printed as soon as the contract is awarded.

Obtain IRB approval

The research protocol was reviewed and approved by the NHRC IRB on 22 Feb 2001. We received notification of BUMED approval on 31 Oct 2001 (BUMED ltr 3900 Ser 26H/01U0583 of 31 Oct 01). AMDEX Corporation (for USAMRMC, per Swatson email of 05 Mar 02) forwarded their IRB approval memo to the Contracting Officer on 2 Mar 2002.

Design tracking procedures

Evaluation of the efficacy of the intervention videos will be based on tobacco use and other relevant outcomes one year after the intervention. Thus, accurate and complete participant tracking procedures are critical to the success of the evaluation. All baseline participants will be identified by their completion of the baseline questionnaire, while the date on which they complete the survey will indicate whether they watched the intervention (tobacco cessation) or control video. Following their graduation from basic training, all new Marines are granted liberty for a period of 10 to 30 days, after which time they report to SOI for continued training. The date on which they view the second video at SOI, as well as the type of video they see (intervention or control) will be documented by obtaining the school's weekly inprocessing roster. All participants will be mailed a follow-up survey 3 months after watching the second video; a final follow-up survey will be mailed 12 months after viewing the second video.

There are two main aspects to the tracking procedures. The first involves locating the participant; the second involves the logistics of the mailout process itself. We intend to contact our participants at their commands, rather than at home addresses. Therefore, the primary variable for locating participants will be the USMC Reporting Unit Code (RUC) which is a unique, 5-digit command code reflecting the command to which an individual is currently attached. The RUC is linked with a second code, a 3-character alpha-numeric Monitored Command Code (MCC). Both codes are needed to identify the correct command address, and both codes are part of each individual's record on the electronic USMC Enlisted Personnel File. By matching the SSNs of our participants to the Enlisted Personnel File, we will be able to download these locator codes, which will then be matched to the USMC Command Address File to obtain the current mailing address for that command.

The Address File is updated quarterly; data on the Enlisted File are updated daily and will be made available to us as an electronic file at least monthly (we are checking on the possibility of receiving an updated file every two weeks). Individuals for whom we are unable to obtain a valid address will be sought via individual SSN queries to the Military Locator System. Discharge data are available on the Enlisted Personnel File, so participants who are discharged from the Marine Corps will be identified and will no longer be tracked for the study.

The electronic files are housed at the Defense Manpower Data Center (DMDC) in Monterey, CA, and accessed through DMDC's IBM computer system. Our staff have been assigned passwords that enable us to access that computer system and its resident files from our desktop PC stations at NHRC. In addition, NHRC employs in-house ADP support staff who work with these files on a daily basis and are able to assist with any access or tracking problems.

The second element in the tracking process involves the follow-up mailout procedures, which involve the following steps:

- (1) Baseline questionnaire data will be entered weekly into a cumulative electronic data file, and participant identifiers will be entered into an accompanying tracking file.
- (2) As each weekly wave of baseline participants reach their 3-month follow-up due date, we will download Name, SSN, Rank, and Email Address (if one has been provided on the survey) for that week's participants. This is File A.
- (3) For those participants who have provided an email address, we will issue an electronic (email) invitation to complete the follow-up survey online. Responders' data will be automatically entered into a data file, and their status as responders will be documented in the electronic tracking ("tickle") file. After three days, a reminder will be emailed to all nonresponders. Anyone who replies to the email invitation saying they do not wish to participate at all will be documented as a study dropout.
- (4) After five working days, all electronic responders, discharges, and refusals will be removed from File A to produce File B. File B will be matched by SSN to the current Enlisted Personnel File to obtain the most recent RUC/MCC and discharge data for the participants. We will then match by RUC/MCC to the Command Address File to obtain a current mailing address for each participant on File B. These participants will be mailed a follow-up survey. The survey cover letter also will offer participants the option of answering the questionnaire online.
- (5) All mail returns will be documented in the tickle file as either completed, declined to participate, or not located. If a participant was not located, we will attempt to find a different address and remail. We will continue to monitor the online survey website to identify electronic responders.
- (6) After approximately 3 weeks, all responders, discharges, and refusals will be removed from File B to create an updated file of nonresponders, or File C. File C will be matched to the most updated Enlisted File and Address File. After a final check in the tickle file to confirm that the participant is indeed a nonrespondent, a tickle postcard will be mailed to members of File C.
- (7) Finally, after another 2 weeks, responders, discharges, and refusals will be removed from File C to create File D; File D will be matched to the updated Enlisted and Address

files; nonresponse status will be confirmed against the tickle file; and the participants will be mailed a second survey packet.

- (8) Throughout this process, incoming data, whether electronic or mailed, will be logged manually into the composite tickle file, and data will be entered weekly into a series of data files.
- (9) This process will be repeated for each new group of study participants as they are enrolled in the study at MCRD on a weekly basis for approximately 52 weeks.
- (10) The same procedures will be used for the 12-month follow-up survey.

KEY RESEARCH ACCOMPLISHMENTS

- Completed literature review of tobacco cessation issues and research.
- Briefed RTR, MCRD, San Diego, and SOI, Camp Pendleton and received approval to conduct the study at those commands.
- Received IRB approval from NHRC, BUMED, and USAMRMC.
- Conducted informal "search and discover" discussions with young Marines at Camp Pendleton, CA, and Camp Lejeune, NC.
- Completed and received approval for two tobacco-cessation video scripts.
- Completed filming of two tobacco-cessation videos (final editing nearly complete).
- Reviewed relevant off-the-shelf health promotion videotapes and selected two nontobacco control videos.
- Developed baseline data collection instrument.
- Designed tracking and mailout procedures for follow-up survey evaluation.

REPORTABLE OUTCOMES

None. (Data collection has not yet begun.)

CONCLUSIONS

The DoD spends an estimated \$875 billion annually in tobacco-related health care and lost productivity.³ Thus, the development of cost-effective intervention strategies for tobacco control is essential. Although the military offers intense clinical tobacco-cessation programs through hospitals, base clinics, and counseling and assistance centers, they are too costly and time-consuming to implement at a population level, particularly during basic training. Yet it is precisely during basic training and shortly thereafter that an intervention to reduce or eliminate tobacco use could reap the most benefits in terms of potential lifelong abstinence. Moreover, the enforced ban on all tobacco products during recruit training affords a head start for quitting as well as a strong new values platform from which to launch an intervention program.

The videos developed during the first year of this project provide a brief, standardized, pre-packaged intervention tailored specifically for Marine Corps recruits. They have been

designed for easy administration to large groups of Marines and for efficient integration with existing MCRD and SOI curriculum schedules. The intervention builds on the existing tobacco ban by providing cognitive and behavioral skills to help motivate and support recruits in maintaining their tobacco abstinence.

Data collection to test the efficacy of the video intervention will begin shortly; preliminary 3-month follow-up results will be available in FY03. The payoff for this minimal, population-based intervention could be substantial, as a significant reduction in tobacco use among these incoming military cohorts could ultimately result in Corps-wide improvements in health, military bearing, performance, and operational readiness.

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APPENDICES

- A. Consent Form
- B. Baseline Questionnaire

APPENDIX A

Informed Consent for Voluntary Participation in a Tobacco Use Study

1. **Introduction:** You have been asked to voluntarily participate in a research project entitled *Tobacco Cessation Intervention for U.S. Marine Corps Recruits*, being conducted at the Marine Corps Recruit Depot (MCRD) in San Diego, CA, and the School of Infantry (SOI) at Camp Pendleton, CA, in collaboration with the Naval Health Research Center, San Diego. You can choose not to participate now or stop at any later time and there will be no penalty or loss of benefits to you if you refuse to participate in this study.
2. **Purpose of Study:** The purposes of this research project are (1) to better understand the use of tobacco by Marine Corps recruits, and (2) to develop and test ideas on how best to provide help for recruits to stop using tobacco.
3. **Description of Study:** You will watch two short training videos (one at MCRD, the other at SOI) that are related to healthy behavior. Each video will last about 15 minutes. At each facility, some platoons will be randomly assigned to watch Video A, others will watch Video B. We are trying to find out if these videos help reduce tobacco use in the Marine Corps. Therefore, you will also be asked to complete a brief questionnaire concerning your smoking habits now, and you will receive two other questionnaires by mail at a later date – one in about 3 months, the other in about a year. It should only take you about 5 minutes to complete the questionnaires. Your honest responses on the questionnaires will help us determine whether the videos have any effect (positive or negative) on tobacco use. Approximately 15,000 recruits will be enrolled in the study.
4. **Benefits:** The benefits to you of participating in this study might include (1) receiving information that might improve your health now or in the future, (2) receiving information that might improve your military performance and readiness now or in the future, and (3) contributing to the development of a scientific program to help reduce tobacco addiction in the Marine Corps.
5. **Risks or Discomforts:** The questions about your tobacco use could make you a little uneasy about your personal lifestyle habits (such as smoking), but there are no significant risks involved in viewing the videos or completing the questionnaires. Participants will be temporarily identifiable and could conceivably be embarrassed to have their tobacco use history discovered by another party, or there may be other risks that are currently unforeseeable. However, these very small risks will be mitigated by measures to ensure confidentiality (see next paragraph).
6. **Confidentiality:** The surveys that you fill out will be kept completely confidential and used for research purposes only. They will be stored in locked cabinets or sealed boxes at the Naval Health Research Center for 5 years, after which time they will be shredded or burned. Your questionnaire responses will be grouped with all other participants' responses into statistical data files; you will NOT be individually identified in any analysis or presentation of study results. Your social security number (SSN) is needed to link your questionnaires together, but once the records are linked, your name and SSN will be removed from the database. (A file containing *only* SSNs will be constructed to provide a record of who participated in the study.) Raw data forms will be accessed only by researchers associated with this project (it should be noted that representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as part of their responsibility to protect human subjects in research.). Complete confidentiality of health data cannot be promised to subjects who are military personnel because information bearing on your health may be required by appropriate medical or command authorities.

7. **Alternative Procedures:** If you are a tobacco user, it might be beneficial for you to discuss this usage with your doctor.

8. **Investigators:** This research is being conducted by Linda K. Trent, M.A., and her colleagues at the Naval Health Research Center. If you have questions about the science of this research, you should contact Linda Trent at (619) 553-8464. If you have questions about the ethical aspects of this study, your rights as a volunteer, or any problem related to protection of research volunteers, you may contact the ombudsman present or else the Chairperson, Committee for Protection of Human Subjects, at the Naval Health Research Center, (619)553-8465.

9. **Informed Consent Record:** The primary investigator in this study is responsible for storage of your consent form and research records related to your participation in this study. These records are stored at the Naval Health Research Center in San Diego, CA 92186-85122

10. **Informed Consent Agreement:** You understand that your willingness to participate in this study is based on information contained in this consent document, which you have read and understood. By your signature, below, you give your voluntary and informed consent to participate in the research as it has been explained to you in this consent form.

Volunteer's Signature: _____ **Date:** _____

Permanent Mailing Address: Name: _____

(for follow-up mailout)

Street: _____

City, State, ZIP: _____

I certify that I have received a copy of this consent form:

Participant's Initials

PRIVACY ACT STATEMENT

1. Authority. 5 U.S.C. 301

2. Purpose. Medical research information will be collected in an experimental research project # 32236, titled, "Tobacco Cessation Intervention for U.S. Marine Corps Recruits," to enhance basic medical knowledge, or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury, or performance impairment.

3. Routine Uses. Medical research information will be used for analysis and reports by the Departments of the Navy and Defense, and other U.S. Government agencies. Use of the information may be granted to non-Government agencies or individuals by the Navy Surgeon General following the provisions of the Freedom of Information Act or contracts and agreements. I voluntarily agree to its disclosure to agencies or individuals identified above, and I have been informed that failure to agree to this disclosure may make the research less useful. The "Blanket Routine Uses" that appear at the beginning of the Department of the Navy's compilation of medical databases also apply to this system.

4. Voluntary Disclosure. Provision of information is voluntary. Failure to provide the requested information may result in failure to be accepted as a research volunteer in an experiment, or in removal from the program.

APPENDIX B**Baseline Tobacco Questionnaire for Marine Recruits**

This information is strictly for research purposes, to be reported in terms of summary statistics; confidentiality of individuals will be protected to the fullest extent under the law. **Privacy Act Statement:** (1) Authority: 5 U.S.C. 301. (2) Purpose: to develop procedures to improve the prevention of illness, injury, and performance impairment. It is hoped that survey respondents will also participate in follow-on study activities. (3) Routine Uses: analysis and reports by the Departments of the Navy and Defense, and other U.S. Government agencies. Use of the information may be granted to non-Government agencies or individuals by the Navy Surgeon General following the provisions of the Freedom of Information Act or contracts and agreements. (4) Disclosure: Voluntary; No penalty will accrue to an individual for not supplying any requested information.

1. Name: _____
(print) Last First

2. Platoon Number: _____

3. Social Security Number: _____ - _____ - _____

4. E-mail address you might be able to be reached at 3 months from now: _____

5. Today's Date: ____ / ____ / 200 ____
Month Day Year

6. Your Age Today: ____

7. Race/Ethnicity: (Circle one number.)

1. White
2. Black or African American
3. Hispanic
4. American Indian or Alaska Native
5. Asian (e.g., East Indian, Chinese, Filipino, Japanese, Korean, Vietnamese)
6. Native Hawaiian or other Pacific Islander (e.g., Samoan, Guamanian, Chamorro)
7. Other (specify): _____

8. Marital Status:

1. Single, never married, and not living as married
2. Separated/divorced/widowed and not living as married
3. Married or living as married

9. Current Level of Education:

1. Less than 12 years (did not finish high school)
2. High school diploma or equivalent
3. Some college or technical school
4. Completed college or technical school

10. Not counting yourself, does anyone in your household (spouse/partner, parents, siblings, etc.) currently use tobacco?

1. Yes
2. No

11. Do most of your close friends at home currently use tobacco?

1. Yes
2. No

12. Have you ever used tobacco, even once or twice just to experiment?

1. Yes
2. No

13. Did you use any tobacco product (cigarettes, cigars, pipe, chew, dip, etc.) in the 30 days before entering recruit training?

1. Yes
2. No

14. Have you ever used tobacco regularly (even if not every day)?

1. Yes
2. No

15. Have you smoked at least 100 cigarettes (5 packs) in your lifetime?

1. Yes
2. No

16. Have you used smokeless tobacco (chew, snuff, dip, pouches, etc.) at least 20 times in your entire life?

1. Yes
2. No

17. How old were you when you first started using tobacco regularly? ____ years old
(If you have never used regularly, answer "0".)

18. Before entering recruit training, had you ever tried to stop using tobacco for 24 hours or more?

1. Not applicable
2. No
3. Yes → How many times? ____

19. If you consider yourself a tobacco user, would you like help quitting tobacco if the help was convenient?

1. I don't consider myself a tobacco user
2. No
3. Yes

20. Before you started recruit training, when was the last time you used tobacco regularly?

1. I never used tobacco regularly
2. Within few days before starting recruit training
3. A week to a month before
4. Between 1 month and 1 year before
5. More than 1 year before

21. When you last used tobacco regularly, how soon after waking up in the morning did you usually have your first smoke or dip?

1. I never used tobacco regularly
2. Immediately
3. Within 15 minutes
4. Within 30 minutes
5. Within an hour
6. More than an hour after waking up

22. When you last used tobacco regularly, how much per day did you usually use? (If none, enter "00" please.)

a. Cigarettes: ____

b. Cigars: ____

c. Pipe Bowls: ____

d. Smokeless (chew, snuff, pouches, dip, etc.): ____

e. Other (specify): ____

- | | Definitely
<u>Not</u> | Probably
<u>Not</u> | Not
<u>Sure</u> | Probably
<u>Yes</u> | Definitely
<u>Yes</u> |
|---|--------------------------|------------------------|--------------------|------------------------|--------------------------|
| 23. Do you think that any of your platoon leaders use tobacco? ----- | 1 | 2 | 3 | 4 | 5 |
| 24. Do you think the ban on tobacco during recruit training is a good idea? ----- | 1 | 2 | 3 | 4 | 5 |
| 25. Are you planning to use tobacco after you graduate recruit training? ----- | 1 | 2 | 3 | 4 | 5 |
| 26. Do you see yourself using tobacco a year from now? ----- | 1 | 2 | 3 | 4 | 5 |
| 27. Do you believe that tobacco use negatively affects the user's health? ----- | 1 | 2 | 3 | 4 | 5 |
| 28. Do you believe that tobacco use negatively affects the user's
overall ability to perform physically? ----- | 1 | 2 | 3 | 4 | 5 |

29. Recalling the 30 days before you entered recruit training, how much were you bothered by...
- | | <u>Often</u> | <u>Sometimes</u> | <u>Seldom</u> | <u>Never</u> |
|---|--------------|------------------|---------------|--------------|
| a) Feeling down, depressed, or hopeless? ----- | 1 | 2 | 3 | 4 |
| b) "Nerves" or feeling anxious or on edge? ----- | 1 | 2 | 3 | 4 |
| c) Little interest or pleasure in doing things? ----- | 1 | 2 | 3 | 4 |
| d) Worry about a lot of different things? ----- | 1 | 2 | 3 | 4 |

30. Before starting recruit training, how often did you engage in physical exercise that lasted for at least 20 minutes nonstop and was hard enough to make you breathe heavier and your heart beat faster?
1. Less than once a week
 2. 1-2 times a week
 3. 3-4 times a week
 4. 5 or more times a week

31. During recruit training, did you experience any symptoms from tobacco withdrawal (cravings for nicotine, headaches, irritable/agitated, unable to concentrate, etc.)?
1. No symptoms at all
 2. A few symptoms
 3. A lot of symptoms
 4. Regular severe symptoms

32. Imagine that you are a tobacco user right now (even if you've never used it). Circle the one statement below that best describes how you feel about your situation:
1. I would quit immediately.
 2. I would try to quit within the next 30 days.
 3. I would seriously consider quitting within the next 6 months.
 4. I would have no plans to quit within the next 6 months.

33. Please choose one of the following statements about yourself:
1. I see myself as a tobacco user; I am just not using it right now (in recruit training).
 2. I see myself as a non-user; I wouldn't use tobacco even if I could.

34. What was the situation that prompted you to start using tobacco after recruit training? (*Select best one.*)

- 1.. I did not use tobacco after recruit training.
2. Drinking alcohol.
3. Friends using tobacco.
4. Friends drinking alcohol and using tobacco.
5. Withdrawal symptoms.
6. Major life event.
7. Everyday stress.
8. Boredom/Routine.
9. I never intended to stay quit.
10. Experimentation.
11. Poor mood (e.g., angry, depressed, anxious).

35. What is the reason you are not currently using tobacco regularly?

- | <u>Yes</u> | <u>No</u> | |
|------------|-----------|---|
| 1 | 0 | |
| ___ | ___ | (<i>Mark <u>all</u> that apply.</i>) |
| ___ | ___ | Short term health reasons (e.g, fitness, mouth sores) |
| ___ | ___ | Long-term health reasons(e.g, cancer, heart disease) |
| ___ | ___ | Pressure from friends. |
| ___ | ___ | Pressure from family. |
| ___ | ___ | Not compatible with Marine Corps values. |
| ___ | ___ | Help advance military career. |
| ___ | ___ | Too expensive. |
| ___ | ___ | Not interested in using tobacco any more. |
| ___ | ___ | Lifestyle changes |
| ___ | ___ | Religious reasons |
| ___ | ___ | Don't enjoy it |
| ___ | ___ | Never interested in using tobacco. |
| ___ | ___ | Other reason: |

THANK YOU FOR YOUR PARTICIPATION!